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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

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ART UNIT

PAPER NUMBER

1642

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/340,196	Applicant(s) Kato et al.
Examiner Jennifer Nichols, Nee Hunt	Group Art Unit 1642



Responsive to communication(s) filed on _____.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 1-18 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 are unclear in the recitation of “a specific sugar chain structure”. The metes and bounds of a specific sugar chain structure cannot be determined. The structure, properties and characteristics exhibited by a specific sugar structure cannot be determined.

Further, claims 1-18 are unclear in the recitation of having. The term “having” is indefinite because the metes and bounds of the claimed invention cannot be determined. In the absence of an express definition in the specification, it cannot be determined if “having” is

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narrow or open ended. For the purpose of examination, it will be given it's broadest reasonable interpretation, which is open ended.

Claims 1-7, 9-11, and 15-18 are unclear in the recitation of thyroglobulin(s). The metes and bounds of thyroglobulin(s) cannot be determined because it is unclear how many thyroglobulin the claim encompasses and what qualities are exhibited by them.

Claims 1-7 and 11 are unclear in the recitation of "each one or more kinds of proteins". It is unclear what proteins are included and what are excluded in the scope of the claims as recited.

Claims 1-7, 11, and 18 are unclear in the recitation of a "constant region". The metes and bounds of a constant region cannot be determined. The qualities and properties encompassed by a constant region are not clear, in that the size or sequence of the regions encompassed cannot be determined.

Claims 1-7, 11 and 18 are unclear in the recitation of "proteins...which bind". The scope of said proteins cannot be determined. The specification fails to teach what "proteins" excludes or what properties are definitive of a protein that binds.

Claims 1-5 and 8-18 are incomplete because they omit essential steps. See MPEP § 2172.01. While all of the technical details of the method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced.

The minimum requirement for method steps should at least include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection

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step in which the reaction steps are quantified or visualized and a correlation step describing how the results of the assay allow the determination. In the instant case, the claims fail to recite a contacting step, a detection step, or a correlation step, for example, correlating how the amount of thyroglobulins corresponds to thyroid malignancy.

Claims 2, 10 and 17 are unclear because the molecules recited as “thyroglobulin(s)”, “specific sugar chains”, and “sugar chain structure other than the specific sugar chain structure” cannot be differentiated.

Claims 6 and 7 are improper because they are of identical scope. Intended use does not lend patentable weight to a composition claim.

Claims 8-16 are unclear in the recitation of “one or more of thyroglobulin”. It is unclear what thyroglobulin are included and what are excluded in the scope of the claims as recited.

Claims 8-18 are unclear in the recitation of “originated from a living body”. The metes and bound of the living body cannot be determined. It is unclear what scope the body encompasses.

Claims 8-18 recite the limitation "the basis". There is insufficient antecedent basis for this limitation in the claim.

Claims 8-16 recite the limitation "the amounts". There is insufficient antecedent basis for this limitation in the claim.

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Claims 9 and 17 recite the limitation "the proportion". There is insufficient antecedent basis for this limitation in the claim. Further, the recitation of "the proportion" is unclear because it cannot be determined what actions are encompassed by "related".

Claims 10-18 recite the limitation "the difference". There is insufficient antecedent basis for this limitation in the claim.

Claims 15-16 are unclear in the recitation of "which is produced by a carcinoma cell". It is not clear what "which" refers to and it therefor cannot be determined what is being produced by said carcinoma cell.

Claims 17 and 18 are unclear in the recitation of "present in a sample...". It is not clear what is described as present in a sample as the claims are recited.

Further, claims 17 and 18 are unclear in the recitation of "differences between or among their sugar chain structures". The metes and bounds of between or among cannot be determined. It is not possible to determine what scope is encompassed by "differences between or among".

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Maruyama et al., Arch. Pathol Lab Med, Vol 122, August 1998.

Maruyama et al. teaches a method of measuring thyroglobulin and detecting malignancy from a sample from a living body by using proteins which bind to a constant region and lectins

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which bind a specific sugar chain structure, where the specific sugar chains are D-galactose, D-mannose, or N-acetyl-D-galactosamine. The specific lectins Concanavalin A, *Ricinus communis*, and *lens culinaris* agglutinin are taught.(page 716, 1st paragraph). Maruyama et al. also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma.(see abstract)

5. Claims 1-2 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by SAR van de Graaf et al, European Journal of Endocrinology, 1997.

SAR van de Graaf et al. teaches a method of measuring thyroglobulin from a sample from a living body by using proteins which bind to a constant region and lectins which bind a specific sugar chain structure. (Page 512, 2nd paragraph)

6. Applicant cannot rely upon the foreign priority papers to overcome these rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

7. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanham et al. Biochemica et Biophysica Acta, Vol 884, 1986.

Hanham et al. teaches a method of measuring thyroglobulin and detecting malignancy from a sample from a living body by using proteins which bind to a constant region and lectins which bind a specific sugar chain structure, where the specific sugar chains are D-galactose, D-mannose. The specific lectins Concanavalin A, *Ricinus communis*, and are taught.(see abstract,

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page 158, 2nd paragraph, and 164 whole page). Hanham et al. also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma.(page 158, 2nd paragraph)

8. Claims 1-3, 5-12, and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tarutani et al, Journal of Biochemistry, Vol 98, pages 851-857, 1985.

Tarutani et al. teaches a method of measuring thyroglobulin and detecting malignancy from a sample from a living body by using proteins which bind to a constant region and lectins which bind a specific sugar chain structure, including Concanavalin A. Tarutani et al also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma via comparison of total thyroglobulin lectin binding and modified thyroglobulin lectin specificity.(see abstract)

9. Claims 1-3, 6-12, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al., Chung-hua Ping Li Hsueh Tsa Chin, Volume 19, No 2, pages 90-93.

Wang teaches a method of measuring thyroglobulin and detecting malignancy from a sample from a living body by using proteins which bind to a constant region and lectins which bind a specific sugar chain structure. Wang et al also teaches the specific reagent of the method, separation of the thyroglobulin, and the specific determination of thyroid carcinoma.(see abstract)
No claims are allowed.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Nichols, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[paulahutzell@uspto.gov\]](mailto:paulahutzell@uspto.gov).

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

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Jennifer Nichols, Nee Hunt

December 29, 1999



YVONNE EYLER, PH.D
PRIMARY EXAMINER